



JCO2 Rec'd PCT/PTO 16 SEP 2005

**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

**Akira TSUJI et al**

Conf. No.: 0000

Appln. No.: 10/541,019

Group Art Unit: 0000

Filed: June 28, 2005

Examiner: Unassigned

For: **GASTROINTESTINAL ABSORPTION ENHANCER MEDIATED BY  
PROTON-COUPLED TRANSPORTER AND ITS PREPARING METHOD**

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants hereby notify the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

A copy of each of the listed documents (except U.S. patents, patent publications and/or non-provisional applications), along with the corresponding International Search Report (indicating the degree of relevance found by the foreign patent office for the references listed therein) dated March 9, 2004, is submitted herewith.

Additionally, the Examiner is requested to note that the references not cited in the above-noted International Search Report are cited in the present specification.

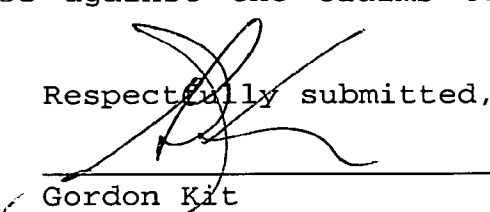
This Information Disclosure Statement is being filed before three months from the application's filing date. Therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.P./

**INFORMATION DISCLOSURE STATEMENT**  
**U.S. Appln. No. 10/541,019**

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Respectfully submitted,



Gordon Kit  
Registration No. 30,764

**SUGHRUE MION, PLLC**  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: September 16, 2005

Substitute for Form 1449 A & B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	10/541,019
				Confirmation Number	0000
				Filing Date	June 28, 2005
				First Named Inventor	Akira TSUJI et al
				Art Unit	0000
				Examiner Name	Unassigned
				Attorney Docket Number	Q-88424
Sheet	1	of	1		

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
		WO	03/000285		01/03/2003	Japan Science and Technology Corp.	Search Rep
		WO	91/16042		10/31/1991	Eurand International SPA	
		EP	612520		08/31/1994	Pfizer Inc	
		WO	00/32172		06/08/2000	Kanji TAKADA	

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		Sakamoto et al, <i>J. Antibiot.</i> , 38:496-504 (1985)	
		Kelly et al, <i>Clin. Pharmacokinet.</i> , 19:177-196 (1990)	
		Swenson et al, <i>Adv. Drug Del. Rev.</i> , 8:39-92 (1992)	
		Kompella et al, <i>Adv. Drug Del. Rev.</i> , 46:211-245 (2001)	
		Hayakawa et al, <i>Pharm. Res.</i> , 9:535-540 (1992)	
		Zhou et al, <i>J. Control Rel.</i> , 29:239-252 (1994)	
		Terao et al, <i>J. Pharm. Pharmacol.</i> , 53:433-440 (2000)	
		Tsuji et al, <i>Pharm. Res.</i> , 11:30-37 (1994)	
		Davies et al, <i>Pharm. Res.</i> , 10:1093-1095 (1993)	
		Barr et al, <i>J. Pharm. Sci.</i> , 59:154-163 (1970)	
		Fei et al, <i>Nature</i> , 368:563-566 (1994)	
		Bradford, <i>Analytical Biochemistry</i> , 72:248-254 (1976)	
		Kitagawa et al, <i>Biol. Pharm. Bull.</i> , 22(7):721-724 (1999)	
		Guo et al, <i>J. of Pharmacology and Exp. Therapeutics</i> , 289(1):448-454 (1999)	
		Tsuji et al, <i>J. of Pharmaceutical Sciences</i> , 79(12):1123-1124 (1990)	
		Ranaldi et al, <i>Antimicrobiol Agents and Chemotherapy</i> , 38(6):1239-1245 (1994)	
		Thwaites et al, <i>British J. of Pharmacology</i> , 115:761-766 (1995)	
		Oh et al, <i>J. of Pharmaceutical Sciences</i> , 91(12):2579-2587 (2002)	
		Barr et al, <i>J. of Pharmaceutical Sciences</i> , 59(2):154-163 (1970)	
		Yoshitomi, "Fundamental Experiment on Gastrointestinal Absorption", <i>Biopharmaceutics Experimental Manual</i> , Shigeru Goto (editor), Tokyo: Seishi Syoin, pages 2-22 (1985)	(See Pg 12, ¶1 of the Spec)
		Tamai, <i>J. of Pharmaceutical Society of Japan</i> , 117(7):415-434 (1997)	Search Report
		Tsuji, <i>Dai 122 Nenka</i> , The Pharmaceutical Society of Japan Koen Yoshishu-1, The Pharmaceutical Society of Japan, page 40 (2002)	Search Report
		Tamai, <i>Advances in Pharmaceutical Sciences</i> , 16:77-87 (2000)	Search Report
		Tamai, <i>Xenobiotic Metabolism and Disposition</i> , 14(2):158-170 (1999)	Search Report
		Sai et al, <i>Igaku no Ayumi</i> , 197(1):23-31 (2001)	Search Report
		DDS Gijutsu no Shinpo, Japan Technology Transfer Association et al, ISBN4-8407-1834-2, pages 137-160 (1990)	Search Report

Examiner Signature	/Jeffrey Palenik/	Date Considered	03/03/2008
--------------------	-------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. <sup>3</sup>Enter Office that issued the document by the two-letter code (WFO Standard 3.1.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the design of the inventor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WFO Standard 3.1.1. If possible, Applicant is to indicate here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE INDICATED OTHERWISE J.P./